http://www.immunize.org/catg.d/4038myth.htm

Vaccine Concerns

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It seems that almost every month newspaper articles and television programs depict the horrors of vaccines. The villains of these stories are greedy vaccine manufacturers, disinterested doctors, and burdensome regulatory agencies. The focus of the stories is that children are hurt unnecessarily by vaccines, and the tone is one of intrigue and cover-up.

Perhaps the most dangerous part of these stories (apart from the fact that they may cause many children to miss the vaccines they need) is that the explanations are presented in a manner that seem believable. Below we have listed the most commonly aired stories about vaccines and have tried to separate fact from myth.

CONCERN: Vaccines don't work.

Probably the best example of the impact of vaccines is the vaccine that prevents meningitis caused by the bacterium *Haemophilus influenzae* type b (Hib).

The current Hib vaccine was first introduced to this country in 1990. At that time Hib was the most common cause of bacterial meningitis, accounting for approximately 15,000 cases and 400 to 500 deaths every year. The incidence of cases and deaths per year had been steady for decades. After the current Hib vaccine was introduced, the incidence of Hib meningitis declined to fewer than fifty cases per year! The power of the Hib vaccine is that most pediatricians and family practitioners working today saw its impact.

The story of the Hib vaccine is typical of all widely used vaccines. A dramatic reduction in the incidence of diseases such as measles, mumps, German measles, polio, diphtheria, tetanus, and pertussis occurred within several years of the introduction of vaccines against them.

Vaccines not only work, but they work phenomenally well.

CONCERN: Vaccines aren't necessary.

In some ways, vaccines are victims of their own success. Most young parents today have never seen a case of measles, mumps, German measles, polio, diphtheria, tetanus, or whooping cough. As a result, some of these parents question the continued need for vaccines.

Vaccines should be given for three reasons:

- Some diseases are so prevalent in this country that a decision not to give a vaccine is a decision to risk that disease (for example, pertussis).

- Some diseases are still present in the environment. These diseases continue to occur, but at fairly low levels (for example, measles, mumps, and German measles). If immunization rates drop, outbreaks of these diseases will again occur and children will die from our lack of vigilance. This is exactly what happened in the late 1980s and early 1990s when immunization rates against measles dropped. The result was 11,000 hospitalizations and more than a hundred deaths caused by measles. Now, due to an increase in measles immunization rates, there are only about a hundred cases of measles and no deaths every year in the United States.

- Some diseases have been virtually eliminated from this country (such as polio and diphtheria). However, these diseases continue to cause outbreaks in other areas of the world. Given the high rate of international travel, these diseases could be easily imported by travelers or immigrants.

CONCERN: Vaccines are not safe.

What does the word safe mean?

The first definition of the word safe is "harmless." This definition would imply that any negative consequences of vaccines would make the vaccine unsafe. Using this definition, no vaccine is 100 percent safe. Almost all vaccines can cause pain, redness, or tenderness at the site of injection. And some vaccines cause more severe side effects. For example, the pertussis (or whooping cough) vaccine can be a very rare cause of persistent, inconsolable crying or high fever. Although none of these severe symptoms results in permanent damage, they can be quite frightening to parents.

But, in truth, few things meet the definition of "harmless." Even everyday activities contain hidden dangers. For example, each year in the United States, 350 people are killed in bath- or shower-related accidents, 200 people are killed when food lodges in their windpipe, and 100 people are struck and killed by lightning. However, few of us consider eating solid food, taking a bath, or walking outside on a rainy day as unsafe activities. We just figure that the benefits of the activity clearly outweigh its risks.

The second definition of the word *safe* is "having been preserved from a real danger." This definition implies that vaccines provide safety. Using this definition, the danger (the disease) must be significantly greater than the means of protecting against the danger (the vaccine). Or, said another way, a vaccine's benefits must clearly and definitively outweigh its risks.

To better understand the definition of the word safe when applied to vaccines, let's examine four different vaccines and the diseases they prevent.

Is the hepatitis B vaccine safe?

The hepatitis B vaccine has few side effects. However, one side effect is serious. About one of every 600,000 doses of hepatitis B vaccine is complicated by a severe allergic reaction called anaphylaxis. The symptoms of anaphylaxis are hives, difficulty breathing, and a drop in blood pressure. Although no one has ever died because of the hepatitis B vaccine, the symptoms of anaphylaxis caused by the vaccine can be quite frightening.

On the other hand, every year thousands of people die soon after being infected with hepatitis B virus. In addition, tens of thousands of people every year suffer severe liver damage (called cirrhosis) or liver cancer caused by hepatitis B virus. Children are much more likely to develop these severe and often fatal consequences of hepatitis B virus infection if they get infected when they are very young. For this reason, the hepatitis B vaccine is recommended for newborns.

Some parents wonder whether it is necessary to give the hepatitis B vaccine to newborns. They ask, "How is a baby going to catch hepatitis B?" But before the hepatitis B virus vaccine, every year in the United States thousands of children less than ten years of age caught hepatitis B virus from someone other than their mothers. Some children caught it from another family member, and some children caught it from someone outside the home who came in contact with the baby. About 1 million people in the United States now are infected with hepatitis B virus. However, because hepatitis B virus can cause a silent infection (meaning without obvious symptoms), many people who have hepatitis B virus infection don't even know that they have it! So it can be hard to tell who might be contagious. Worse yet, you can catch hepatitis B virus after casual contact with someone who is infected (for example, sharing hand towels).

Because the benefits of the hepatitis B vaccine clearly and definitively outweigh the risks, the hepatitis B vaccine is safe.

Was the old pertussis vaccine safe?

The old pertussis vaccine had far more risks than the hepatitis B vaccine. The old pertussis vaccine was called the "whole-cell" vaccine and had a high rate of severe side effects. Persistent, inconsolable crying occurred in one of every 100 doses, fever greater than 105°F occurred in one of every 330 doses, and seizures with fever occurred in one of every 1,750 doses. Due to negative publicity about this vaccine, the use of pertussis vaccine decreased in many areas of the world.

For example, Japan simply stopped using the pertussis vaccine in 1975. In the three years before the vaccine was discontinued, there were 400 cases of pertussis and ten deaths from pertussis. In the three years after the pertussis vaccine was discontinued, there were 13,000 cases of pertussis and 113 deaths! It should be noted that although the side effects of the pertussis vaccine were high, children didn't die from pertussis vaccine. What they did die from was pertussis infection. The Japanese Ministry of Health, realizing how costly their error had been, soon reinstituted the use of pertussis vaccine.

What happened to the children of Japan proved that the benefits of the pertussis vaccine clearly outweighed the risks. Today's new "acellular" pertussis vaccine has a much lower risk of severe side effects than the old "whole-cell" vaccine– therefore, it is even safer.

Was the rotavirus vaccine safe?

The rotavirus vaccine was withdrawn for use because of a problem with safety. The vaccine was found to cause a rare but potentially very serious side effect called intussusception. Intussusception occurs when one section of the small intestine folds into another section of the intestine. When this happens, the intestine can become blocked. Intussusception is a medical emergency, and children can die from the disease. The rotavirus vaccine was given to about 1 million children in the United States between 1998 and 1999. About one of every 10,000 children who were given the vaccine got intussusception (a total of about 100 children), and one child died because of the vaccine.

What happened to children who didn't get the rotavirus vaccine? Of the 1 million children who didn't get the vaccine, about 16,000 were hospitalized with water loss (or dehydration) and about five to ten died from dehydration caused by rotavirus. Many more children were hospitalized and killed by rotavirus infection than were hospitalized and killed by the rotavirus vaccine. So the United States had to choose between the risk of the rotavirus vaccine and the risk of natural infection.

The Centers for Disease Control and Prevention (CDC) and the American Academy of Pediatrics felt that the risk from rotavirus vaccine was simply too great and preferred to wait for a rotavirus vaccine that was safer.

But let us not fool ourselves into thinking that the decision not to use a rotavirus vaccine rendered children free from risk. Because rotavirus disease is common, the choice not to give the rotavirus vaccine was a choice to allow for continued natural infection with rotavirus. This choice meant that children will continue to be at risk of severe and occasionally fatal rotavirus infection.

Is the pneumococcal vaccine safe?

The pneumococcal vaccine was licensed for use in the United States in the year 2000 and was recommended for use in all children less than five years of age. Some parents chose to take a "wait and see" attitude when the vaccine was first licensed. They reasoned that because the problems with the rotavirus vaccine were not revealed until the vaccine was given to 1 million children, why not wait and see what happens after the pneumococcal vaccine is given to at least 1 million or more children?

However, the choice not to give the pneumococcal vaccine was again not a risk-free choice, because every year in the United States thousands of children get meningitis, bloodstream infections, and pneumonia from pneumococcus. So the choice not to give a pneumococcal vaccine was a choice to risk the severe, often permanent, and occasionally fatal, consequences of pneumococcal infection. Parents should be reassured about the safety of this vaccine because of two facts. First, the pneumococcal vaccine was tested in about 20,000 children before being licensed for use. Second, the *Haemophilus influenzae* type b (Hib) vaccine is made in a manner almost identical to the pneumococcal vaccine, and has been given safely to about 3 million children every year since 1990.

Are systems in place to ensure that vaccines are safe after they are licensed?

The rotavirus vaccine is an example of how rare side effects can be detected. The vaccine was tested in about 11,000 children before it was submitted to the Food and Drug Administration (FDA) for licensure. After the vaccine was licensed and recommended for use, the vaccine was given to about 1 million children.

A system called the Vaccines Adverse Events Reporting System (VAERS) then found about fifteen cases of an intestinal blockage called intussusception soon after administration of the vaccine. This was worrisome enough to the CDC to cause them to temporarily suspend use of the vaccine until it could be determined whether the vaccine did, in fact, cause intussusception.

An analysis by the CDC showed that intussusception occurred in about one of every 10,000 children that received the vaccine. Because only 11,000 children had been tested before the vaccine was licensed, it had not been really possible to detect such a rare side effect. The result of the rotavirus vaccine experience is that at least 60,000 children will be tested before the next rotavirus vaccine is licensed.

Several other sources of information about the side effects of vaccines, such as the Vaccine Safety Datalink (VSD), are also available. This database also allows one to determine the "background" rate of side effects, meaning the rate of adverse events in children who don't receive a vaccine. So, in many ways, systems such as the VSD are better than VAERS because they allow one to determine whether a vaccine really did cause a rare side effect.

CONCERN: Infants are too young to get vaccinated.

Children are immunized in the first few months of life because several vaccine-preventable diseases infect them when they are very young. For example:

- Pertussis infects about 8,000 children, causing five to ten deaths every year in the United States. Almost all of the cases are in children *less than one year of age.*

- Children *under two years old* are 500 times more likely to catch Hib meningitis if someone with a Hib infection is living in the home.

- About 90 percent of *newborns* whose mothers are infected with hepatitis B will contract hepatitis and go on to develop chronic liver disease, cirrhosis, and possibly liver cancer.

For these reasons, it is very important for infants to be fully immunized against certain diseases by the time they are six months old.

Fortunately, young infants are surprisingly good at building immunity to viruses and bacteria. About 95 percent of children given DTaP, Hib, and hepatitis B virus vaccines will be fully protected by two years of age.

CONCERN: It's better to be naturally infected than immunized.

It is true that "natural" infection almost always causes better immunity than vaccination (only the Hib, pneumococcal, and tetanus vaccines are better at inducing immunity than natural infection). Whereas natural infection causes immunity after just one infection, vaccines usually create immunity only after several doses are given over a number of years. For example, DTaP, hepatitis B, and IPV are each given at least three times.

However, the difference between vaccination and natural infection is the price paid for immunity. The price paid for vaccination is the inconvenience of several shots and the occasional sore arm. The price paid for a single natural infection is usually considerably greater: paralysis from natural polio infection, mental retardation from natural Hib infection, liver failure from natural hepatitis B virus infection, deafness from natural mumps infection, or pneumonia from natural varicella infection are high prices to pay for immunity.

CONCERN: Children get too many shots.

Infants and young children commonly encounter and manage many challenges to their immune system at the same time. Twenty years ago, seven vaccines were routinely recommended, and children received five shots by two years of age and as many as two shots at one time. Now that we have eleven routinely recommended vaccines, children could receive as many as twenty shots by two years of age and five shots at a single visit. Many parents are concerned about whether children can handle all these vaccines.

But vaccines are just a small part of what babies encounter every day. Although the mother's womb is free from bacteria and viruses, newborns immediately face a host of different challenges to their immune system. For example, from the minute they are born, thousands of different bacteria start to live on the skin as well as the lining of the nose, throat, and intestines. By quickly making an immune response to these bacteria, babies keep the bacteria from invading their bloodstream and causing serious disease.

In fact, babies are capable of responding to millions of different viruses and bacteria because they have billions of immunologic cells circulating in their bodies. Therefore the vaccines given in the first two years of life are literally a raindrop in the ocean of what infants' immune systems successfully encounter in their environment every day.

It is interesting to note that although children receive more vaccines today than they did a hundred years ago, when only the smallpox vaccine was routinely recommended in infancy, the number of separate immunologic challenges contained in vaccines has actually decreased! The smallpox vaccine contained about 200 viral proteins. If you add up today's eleven routinely recommended vaccines, the number of vaccine proteins and polysaccharides (complex sugars) is less than 130: diphtheria (1), tetanus (1), pertussis (2-5), polio (15), measles (10), mumps (9), rubella (5), Hib (2), varicella (69), conjugate pneumococcus (8), and hepatitis B (1).

CONCERN: Vaccines weaken the immune system.

Natural infection with certain viruses can indeed weaken the immune system. This means that when children are infected with one virus, they can't fight off other viruses or bacteria as easily. This happens most notably during natural infection with either chickenpox or measles. Children infected with chickenpox are susceptible to infection with certain bacterial infections (like "flesh-eating" bacteria). And children infected with measles are more susceptible to bacterial infections of the bloodstream (sepsis).

But vaccines are different. The viruses in the measles and chickenpox vaccines (the so-called vaccine viruses) are very different from those that cause measles and chickenpox infections (the "wild-type" viruses). The vaccine viruses are themselves so disabled that they cannot weaken the immune system. Vaccinated children are not at greater risk of other infections (meaning infections not prevented by vaccines) than unvaccinated children.

CONCERN: Vaccines "use up" the immune system.

Is it possible that all the vaccines given to children in the first few months of life use up the immune system? Certainly children build immunity to only a limited number of microorganisms (viruses, bacteria, fungi, or parasites). The question is, How many?

Probably the most sensible approach to answering this question was that formulated by Dr. Mel Cohn and Dr. Rodney Langman, immunologists working at the Developmental Biology Laboratory at the Salk Institute in San Diego. They theorized that the number or microorganisms to which a body can respond depends on the number of cells in blood that can make antibodies sufficient to recognize all the relevant parts of the microorganism.

Using their theory, it stood to reason that the number of microorganisms to which one responds depends on one's size. Cohn and Langman estimated that elephants can produce immunity to about a hundred times more microorganisms than humans, and that humans can build immunity to at least a hundred times more mircroorganisms than hummingbirds. Although this would mean that adult humans could make antibodies to more organisms than infants, the scientists estimated that even young infants could respond to about 100,000 different organisms at one time.

Therefore, the eleven vaccines required for all children will use up only about 0.01 percent of the immunity that is available.

CONCERN: Some vaccines contain other infectious agents that may damage my child.

All currently recommended vaccines are tested by pharmaceutical companies under the strict supervision of the FDA. Vaccines are tested for the presence of known viruses, bacteria, fungi, or parasites different from those contained in the vaccine.

When you consider that the 3.5 to 4 million children born every year in the United States receive eleven different vaccines by the time they are six years old, and that some of these vaccines have been in existence for over fifty years, the record of vaccine safety in this country is remarkable.

CONCERN: Vaccines cause autism.

Recently, stories carried by the media have caused some parents to fear that the combination measles-mumps-rubella (MMR) vaccine causes autism. Summarized below are (1) studies used to support the notion that MMR causes autism, (2) studies that disprove the notion that MMR causes autism, and (3) other investigations into the causes of autism.

The "Wakefield" studies

Two studies have been cited by those claiming that the MMR vaccine causes autism. Both studies are critically flawed.

In 1998, Andrew Wakefield and colleagues published a paper in the journal *Lancet.* Wakefield's hypothesis was that the MMR vaccine caused a series of events that include intestinal inflammation, entrance into the bloodstream of proteins harmful to the brain, and consequent development of autism. In support of his hypothesis, Dr. Wakefield described twelve children with developmental delay, of whom eight had autism. All of these children had intestinal complaints and developed autism within one month of receiving MMR.

The Wakefield paper published in 1998 is flawed for two reasons: (1) About 90 percent of children in England received MMR at the time this paper was written. Because MMR is administered at a time when many children are diagnosed with autism, it would be expected that most children with autism would have received an MMR vaccine, and that many would have received the vaccine recently. The observation that some children with autism recently received MMR is, therefore, expected. However, determination of whether MMR causes autism is best made by studying the incidence of autism in *both* vaccinated and unvaccinated children. This wasn't done.

(2) Although the authors claim that autism is a consequence of intestinal inflammation, intestinal symptoms were observed *after,* not before, symptoms of autism in all eight cases.

In 2002, Wakefield and coworkers published a second paper examining the relationship between measles virus and autism. The authors tested intestinal biopsy samples for the presence of measles virus from children with and without autism. Of children with autism, 75 of 91 were found to have measles virus in intestinal biopsy tissue as compared with only five of 70 patients who didn't have autism.

On its surface, this is a concerning result. However, the second Wakefield paper is also critically flawed for the following reasons: (1) Measles vaccine virus is live and attenuated. After inoculation, the vaccine virus probably replicates (or reproduces itself) about fifteen to twenty times. It is likely that measles vaccine virus is taken up by specific cells responsible for virus uptake and presentation to the immune system (termed antigen-presenting cells, or APCs).

Because all APCs are mobile, and can travel throughout the body (including the intestine), it is plausible that a child immunized with MMR would have measles virus detected in intestinal tissues using a very sensitive assay. To determine whether MMR is associated with autism, one must determine whether the finding is *specific* for children with autism. Therefore, children with or without autism must be identical in two ways. First, children with or without autism must be matched for immunization status (that is, receipt of the MMR vaccine). Second, children must be matched for the length of time between receipt of MMR vaccine and collection of biopsy specimens. Although this information was clearly available to the investigators and critical to their hypothesis, it was omitted from the paper. (2) Because natural measles virus is still circulating in England, it would have been important to determine whether the measles virus detected in these samples was natural measles virus or vaccine virus. Although methods are available to distinguish these two types of virus, the authors did not use them. (3) The method used to detect measles virus in these studies was very sensitive. Laboratories that work with natural measles virus (such as the lab where these studies were performed) are at high risk of getting results that are incorrectly positive. No mention is made in the paper as to how this problem was avoided. (4) As is true for all laboratory studies, the person who is performing the test should not know whether the sample is obtained from a case with autism or without autism (blinding). No statements were made in the methods section to assure that blinding occurred.

Studies showing that MMR vaccine does not cause autism

Four studies have been performed that disprove the notion that MMR causes autism.

In 1999, Brent Taylor and coworkers examined the relationship between receipt of MMR and development of autism in a well-controlled study. Taylor examined the records of 498 children with autism or autism-like disorder. Cases were identified by registers from the North Thames region of England before and after the MMR vaccine was introduced into the United Kingdom in 1988. Taylor then examined the incidence and age at diagnosis of autism in vaccinated and unvaccinated children. He found that (1) the percentage of children vaccinated was the same in children with autism as in other children in the North Thames region; (2) no difference in the age of diagnosis of autism was found in vaccinated and unvaccinated children; and (3) the onset of symptoms of autism did not occur within two, four, or six months of receiving the MMR vaccine.

Subsequent studies by Natalie Smith published in the *Journal of the American Medical Association* and by Hershel Jick in the *British Medical Journal* found that the increase in the number of children reported to have autism was not associated with an increase in the use of the MMR vaccine.

The largest study to examine the relationship between the MMR vaccine and autism was reported in the *New England Journal of Medicine* in November 2002. About 537,000 children in Denmark who either did or did not receive the MMR vaccine were examined for about six years. The incidence of autism was the same in children who did or did not receive the MMR vaccine.

Studies on the causes of autism

One of the best ways to determine whether a particular disease or syndrome is genetic is to examine the incidence in identical and fraternal twins. Using a strict definition of autism, when one twin has autism, approximately 60 percent of identical and 0 percent of fraternal twins have autism. Using a broader definition of autism (that is, autistic spectrum disorder), approximately 92 percent of identical and 10 percent of fraternal twins have autism. Therefore, autism clearly has a genetic basis.

Clues to the causes of autism can be found in studies examining when the symptoms of autism are first evident. Perhaps the best data examining when symptoms of autism are first evident are the "home-movie studies." These studies took advantage of the fact that many parents take movies of their children during their first birthday (before they have received the MMR vaccine). Home movies of children who were eventually diagnosed with autism and those who were not diagnosed with autism were coded and shown to developmental specialists. Investigators were, with a very high degree of accuracy, able to separate autistic from nonautistic children at one year of age.

These studies found that subtle symptoms of autism were present earlier than some parents had suspected, and that receipt of the MMR vaccine did not precede the first symptoms of autism.

Other investigators extended the home-movie studies of one-year-old children to include videotapes of children taken at two to three months of age. Using a sophisticated movement analysis, videos from children eventually diagnosed with autism or not diagnosed with autism were coded and evaluated for their capacity to predict autism. Children who were eventually diagnosed with autism were predicted from movies taken in early infancy. This study supported the hypothesis that very subtle symptoms of autism are present in early infancy and argues strongly against vaccines as a cause of autism.

Toxic or viral insults to the fetus that cause autism, as well as certain central nervous system disorders associated with autism, support the notion that autism is likely to occur in the womb.

For example, children exposed to thalidomide during the first or early second trimester were found to have an increased incidence of autism. However, autism occurred in children with ear but not arm or leg abnormalities. Because arms and legs develop after 24 [days*] gestation, the risk period for autism following receipt of thalidomide must be before 24 [days*] gestation.

In support of this finding, Rodier and colleagues found evidence for structural abnormalities of the nervous system in children with autism. These abnormalities could have occurred only during development of the nervous system in the womb.

Similarly, children with congenital rubella syndrome are at increased risk for development of autism. Risk is associated with exposure to rubella before birth but not after birth.

*IAC has substituted the word “days” for the word “weeks” to correct two typos that occur in this paragraph in the book.

Conclusions

Studies of (1) the genetics of autism, (2) the timing of the first symptoms of autism (home-movie studies), (3) the relationship between autism and the receipt of the MMR vaccine, (4) the nervous system of children with autism, and (5) thalidomide and natural rubella infection all support the fact that autism occurs during development of the nervous system early in the womb.

Unfortunately for parents who will someday bear children diagnosed with autism, the controversy surrounding vaccines has diverted attention and resources away from a number of promising leads.

CONCERN: A mercury-containing preservative (thimerosal) contained in many vaccines harms children.

On October 1, 2001, the Institute of Medicine (IOM) issued a report on the use of thimerosal in vaccines. The IOM advises the federal government on health matters and was established in 1970 by the National Academy of Sciences. The IOM recommended the use of thimerosal-free DTaP, Hib, and hepatitis B vaccines in the United States.

What is thimerosal?

Thimerosal is a preservative that is used in vaccines. It is made of thiosalicylic acid and mercury. The mercury contained in thimerosal is an organic form called ethylmercury.

Why do vaccines contain the preservative thimerosal?

Preservatives such as thimerosal prevent vaccines from ecoming contaminated with bacteria or fungi. Preservatives are especially important when the vial of vaccine contains more than one dose (multidose vials). Studies from about fifty years ago showed that multidose vials of vaccine could become contaminated with bacteria. Bacteria in the vial could then be injected inadvertently into the child and cause serious and occasionally fatal infections.

Is mercury harmful?

Yes. Mercury at high levels can damage the nervous system and kidneys. Studies in places such as the Faroe Islands, the Seychelles, and Iraq found that the unborn fetus might be harmed when pregnant women ingest large quantities of mercury contained in contaminated fish or fumigated (disinfected) grain. The form of mercury that contaminates the environment is called methylmercury (not the ethylmercury contained in vaccines).

Does thimerosal contain an amount of mercury that could harm children?

The FDA was recently required to compile a list of drugs and foods that contained mercury (the FDA Modernization Act of 1997). Because some vaccines contain thimerosal, they were included in the list generated by the FDA. The amount of mercury contained in vaccines was then compared with acceptable levels of mercury published by the FDA, Environmental Protection Agency (EPA), Agency for Toxic Substance and Disease Registry (ATSDR), and World Health Organization (WHO).

Cumulative levels of mercury contained in multiple vaccines were not greater that those considered to be safe by the FDA, WHO, or ATSDR. However, the levels of mercury contained in multiple vaccines did slightly exceed those considered to be safe by the EPA.

How did the EPA determine what levels of mercury were safe for children?

The EPA looked closely at a study performed in Iraq where pregnant women were exposed to large quantities of methylmercury that had been used to fumigate grain. The EPA then estimated the lowest dose of mercury that was found to cause neurodevelopmental delay in the fetus whose mother ingested this seed grain. From this they calculated the lowest dose of methymercury that could possibly harm an unborn child. They then divided this dose by a safety factor of ten to determine the lowest acceptable dose of mercury.

There are many problems with using the study in Iraq to determine levels of thimerosal in vaccines that would be safe in children. First, thimerosal doesn't contain the form of mercury that contaminates the environment. Environmental mercury is usually methylmercury, whereas the mercury contained in vaccines is in the form of ethylmercury. Ethylmercury is excreted in the urine more quickly than methylmercury and is less likely to accumulate in the body. Second, vaccines are administered to children after, not before, they are born. The nervous system of a child is still developing early in a woman's pregnancy, but by the time a child gets a vaccine, the nervous system is more mature and, therefore, much less likely to be susceptible to the harmful effects of mercury. Third, by including a safety factor of ten, the EPA estimate was very conservative.

Has thimerosal contained in vaccines ever been shown to harm children?

No. Studies have never shown that mercury at the level contained in vaccines causes neurological problems.

If thimerosal has never been found to harm children, why are vaccine makers now making vaccines that don't use thimerosal as a preservative?

Thimerosal is being taken out of vaccines for two reasons. First, single-dose vials have largely replaced multidose vials in the United States. Therefore, the risk of contamination with bacteria or fungi is much lower. Second, other preservatives that don't contain any mercury can be used in some vaccines.

So the main reason that thimerosal is being taken out of vaccines is that it can be. Thimerosal (as a preservative) is absent from all vaccines routinely given to children in the United States.

CONCERN: The hepatitis B vaccine causes sudden infant death syndrome (SIDS).

The ABC television program *20/20* aired a story claiming that the hepatitis B vaccine caused SIDS. They showed the picture of a one-month-old girl who had died of SIDS only sixteen hours after receiving her second dose of hepatitis B vaccine. To the reporters of this story, this proved that the hepatitis B vaccine caused SIDS. Although anecdotes can be quite powerful, they can also be misleading.

Every year in the United States, thousands of infants die of SIDS. The hepatitis B vaccine is now routinely recommended for infants as a series of three shots. Therefore, some infants who get the hepatitis B vaccine will invariably die from SIDS—and some will die from SIDS soon after the vaccine is given. But does this mean that children who get the vaccine are more likely to die from SIDS than children who don't get the vaccine?

To really understand if a vaccine causes problems you need more information. You need to know the incidence of SIDS in those who got the vaccine and the incidence of SIDS in those who didn't get the vaccine. Anecdotes do not provide this information. When the incidence of SIDS is examined in immunized and unimmunized infants, there is no evidence that the hepatitis B vaccine causes SIDS.

Indeed, the incidence of SIDS has decreased dramatically since the hepatitis B vaccine was first recommended for all infants. The reason for the decline is that the American Academy of Pediatrics recommended the "Back to Sleep" program for all infants. Parents were asked to let infants sleep on their backs instead of face down. The result was a dramatic decline in SIDS and proved that SIDS was not related to vaccines.

CONCERN: Pharmaceutical companies occasionally manufacture lots of vaccines that cause high rates of adverse events ("hot lots").

Individual lots of vaccines that have unusually high rates of side effects have never been identified in this country. Therefore, specific lots of vaccines have never been withdrawn from use as a "hot lot.

CONCERN: Vaccine-preventable diseases occur more often in vaccinated people than in unvaccinated people.

On its face, this statement is actually true. However, it is important to understand why it is true.

Let's take the situation of 100 young adults living in a college dormitory and say that 95 were vaccinated against measles and five were not vaccinated.

An outbreak of measles strikes the college campus. In the dormitory, six of the 95 people who were vaccinated get measles, and four of the five unvaccinated people get measles. This would mean that vaccinated people get measles more commonly than unvaccinated people (in this case, by a margin of 6 to 4). However, the risk for measles in the unvaccinated group was 80 percent (4 of 5), whereas the risk for measles in the vaccinated group was only about 6 percent (6 of 95). So, people were much less likely to get measles if they had received the measles vaccine.

Indeed, a study recently reported in the *Journal of the American Medical Association* found that unvaccinated people were thirty-five times more likely to get measles than vaccinated people.

CONCERN: The hepatitis B vaccine causes arthritis, multiple sclerosis, and long-term (chronic) neurologic disorders.

A segment of the ABC television show *20/20* told of children and adults who developed arthritis, multiple sclerosis, or neurologic disabilities following receipt of the hepatitis B vaccine. However, if one event precedes another, it did not necessarily cause the other.

For example, multiple sclerosis commonly has its onset in adolescence and early adulthood. Therefore, if the hepatitis B vaccine is given to adolescents and young adults, some will develop multiple sclerosis following receipt of the vaccine. For some, onset of multiple sclerosis could follow soon after receipt of the vaccine and appear to be related. But the only way to determine whether the hepatitis B vaccine caused multiple sclerosis would be to determine the incidence of multiple sclerosis in those who had received the vaccine and the incidence in those who hadn't received the vaccine.

Several studies have been performed to answer this question, and all have reached the same conclusion: the incidence of multiple sclerosis was the same in those who received the hepatitis B vaccine and those who hadn't.

So, why is the hepatitis B vaccine blamed for all these problems? When children or adults suffer, we search desperately for a cause. If we can find a clear, discrete cause, then at least we can help other people avoid what we have suffered. No clear cause for multiple sclerosis, autism, violent behavior, sudden infant death syndrome, hyper-activity, Alzheimer's disease, and many cancers have been found. It's frustrating. And vaccines are an easy target. But venting our frustrations by blaming vaccines, in the absence of any clear evidence that vaccines are the problem, will only endanger our children.

CONCERN: Vaccines cause diabetes.

One researcher claimed that infants immunized with a single dose of the Hib vaccine at fourteen months of age were less likely to get diabetes than if they received four doses of the Hib vaccine at three, four, six, and fourteen months of age. He concluded that the risk of diabetes could be reduced if children did not receive vaccines at a young age. Some parents have seen this information and chosen to wait until their children are two years of age to have them immunized. This is unfortunate, because some vaccine-preventable diseases, such as Hib, pneumococcus, and pertussis, occur commonly in the first two years of life.

A careful review of the data, however, found that the analytic methods used in that study were incorrect. In addition, a ten-year follow-up study showed that the incidence of diabetes was the same in those who had been immunized early and in those who had been immunized later. Further, a recent study by the CDC found that the incidence of diabetes was the same in vaccinated as in unvaccinated children. So, no evidence exists to support the notion that vaccines should be delayed.

CONCERN: The DTP vaccine causes a disease that looks like "shaken baby" syndrome.

Small children who are shaken forcefully in rage can develop bleeding around the brain (subdural hematomas) and bleeding on the back of the eye (retinal hemorrhages). Some lawyers have chosen to defend people accused of abusing children by saying that bleeding was caused by the pertussis component of the DTP vaccine. However, no evidence exists to support this contention. Neither pertussis nor the pertussis vaccine cause bleeding around the brain or on the back of the eye—only forceful shaking does this.

CONCERN: The polio vaccine is the cause of AIDS.

Tom Curtis wrote an article in *Rolling Stone* magazine claiming that the origin of AIDS could be traced to polio virus vaccines that were administered in the Belgian Congo between 1957 and 1960. The explanations behind this assertion were as follows: (1) All virus vaccines are made in cells, (2) the polio virus vaccine was grown in monkey kidney cells, (3) monkey kidney cells used at that time contained a virus (simian immunodeficiency virus, or SIV) similar to the virus that causes AIDS (human immunodeficiency virus, or HIV), and

(4) people were inadvertently inoculated with SIV, which then mutated to HIV and caused the AIDS epidemic.

This reasoning is confounded by several false assumptions. First, although monkeys can be infected by SIV, a disease similar to HIV, SIV is not found in kidney cells. Second, SIV and HIV, although their spelling is very similar, are not genetically very close; mutation to one from the other would require centuries, not years. Third, SIV and HIV, although deadly viruses, are fairly fragile. Both of these viruses, if given by mouth (in a manner similar to the oral polio vaccine), would be rapidly destroyed by the enzymes and acids in the mouth and stomach. Last, original lots of the polio vaccine were recently tested for the presence of HIV using very sensitive tests that were not available in the late 1950s. These tests, called polymerase chain reaction, or PCR, are used today to diagnose HIV infection in children, adolescents, and adults. No HIV was present in any of those lots.

CONCERN: The polio virus vaccine is contaminated with a virus that causes cancer.

It is true that early lots of the polio vaccine used in the late 1950s and early 1960s were contaminated with a monkey virus called simian virus 40, or SV40. Recently, investigators found evidence for the presence of SV40 virus in a type of cancer called lymphoma. However, several facts should be noted. First, SV40 was present in cancers of people who either had or had not received the polio vaccine that was contaminated with SV40. Second, SV40 has not been present in any vaccine since the early 1960s. Third, people with lymphoma who were born after SV40 was no longer a contaminant of the polio vaccine were found to have evidence for SV40 in their cancerous cells. Taken together, these findings suggest that SV40 may be associated with some cancers, but that the virus is transmitted to people by a mechanism other than vaccines.

CONCERN: Vaccines may contain the agent that causes "mad-cow" disease.

On February 8, 2001, the *New York Times* published an article entitled "Five Drug Makers Use Material with Possible Mad-Cow Link." This article followed a Public Health Service statement on December 22, 2000, in *Morbidity and Mortality Weekly Report* (MMWR). MMWR is written by the CDC. The *New York Times* article and CDC report were prompted by the confluence of several events. First, as of July 2000, about 175,000 cows in the United Kingdom developed a disease called "mad-cow" disease—a progressive disease of the nervous system of cattle. Second, at least seventy-three people in the United Kingdom developed a progressive neurological disease called variant Creutzfeld-Jakob disease (vCJD) that may have resulted from eating meat prepared from cows with "mad-cow" disease. Third, some vaccines are made with serum or gelatin obtained from cows in England or from countries at risk for "mad-cow" disease.

What causes progressive neurological diseases such as "mad-cow" disease or vCJD?

vCJD is caused by an unusual protein called a prion (proteinaceous infectious particle). Prions are found in the brains of cows with "mad-cow" disease and in the brains of humans with vCJD. Prions can also be found in the spinal cord and in the back of the eye (retina).

However, blood from infected animals or blood from infected people has never been shown to be a source of infection to humans.

If prions are found only in the brain and spinal cord, why did people in England get vCJD after eating meat from cows?

The likely source of prions for people in England was hamburger, not steak, prepared from cows. Hamburger may be prepared in a manner that includes the spinal cord. Steak, on the other hand, represents only the muscles of cows and, therefore, does not contain prions.

Why do vaccines contain materials derived from cows?

Viral vaccines are weakened forms of natural viruses. Some viral vaccines are made by "growing" viruses in specialized cells in the laboratory. Many growth factors are needed for cells to grow. An excellent source of these growth factors is serum obtained from the fetuses of cows (known as fetal bovine serum). Fetal bovine serum is a naturally filtered source of growth factors. The natural filter is the bovine placenta. Whereas the human placenta contains one and a half layers that separate the mother's blood from fetal blood, the bovine placenta contains six layers. Many proteins are excluded from the bovine fetal circulation by these six layers (for example, bovine fetal blood contains 1/500 of the antibodies found in bovine maternal blood).

Another product from animals (cows or pigs) that may be used in vaccines is gelatin. Gelatin is a protein formed by boiling skin or connective tissue (for example, hooves). Gelatin is used to stabilize vaccines so that they remain effective after manufacture.

Do vaccines that have been exposed to bovine materials during manufacture pose a risk for transmission of vCJD?

To answer this question, let's go through each step of the manufacturing process.

- Cows with "mad-cow" disease have prions in their brain, spinal cord, and retina. However, prions are not detected in their blood, skin, or connective tissue.

- Fetal bovine serum is used in the manufacture of vaccines. Fetal bovine serum is obtained from fetal blood, and blood is not a source of infection with prions. In addition, although cows "share" their blood with their unborn calves, the bovine placenta is a natural filter. Maternal-fetal transmission of prions has *never* been documented in animals.

- Fetal bovine serum is highly diluted and eventually removed from cells during the growth of vaccine viruses.

- Prions are propagated in mammalian brains and *not* in cell culture used to make vaccines. Therefore, prions are unlikely to be propagated in the cells used to grow vaccine viruses.

- Gelatin is also used in the manufacture of vaccines. Gelatin is added to vaccines at the end of the manufacturing process. However, gelatin is made from materials (skin and connective tissue) that do not contain prions. In addition, the preparation of gelatin often includes heat sterilization or treatment with organic solvents. It is likely that these treatments would inactivate prions.

- Transmission of prions occurs from either eating brains from infected animals or, in experimental studies, from directly inoculating preparations of brains from infected animals into the brains of experimental animals. Transmission of prions has *not* been documented after inoculation into the muscles or under the skin (routes used to vaccinate).

When you put all these factors together, the chance that currently licensed vaccines contain prions is essentially zero.

If vaccines pose no risk for progressive neurological diseases, why is the Public Health Service choosing to eventually eliminate bovine-derived materials obtained from countries at risk for "mad-cow" disease?

The Public Health Service is interested in maintaining the public's trust in immunizations. They are concerned that the public may fear that vaccines containing bovine materials from countries at risk for "mad-cow" disease could potentially transmit this disease to children. So they have taken the precautionary steps of eventually eliminating the use of these materials in the production of vaccines. However, the facts about prion transmission should reassure us that it is essentially impossible for currently licensed vaccines to contain prions.

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Top of page